52 (new). A tablet according to Claim 34 wherein the clavulanate is potassium clavulanate.

53 (new). A tablet formulation according to Claim 34 for oral administration twice daily.

54 (new). A method of treating a bacterial infection in a patient in need thereof, which method comprises administering to said patient an effective amount of a formulation according to Claim 34.

REMARKS

Claims 6 to 9 and 16 to 18 are in the application. Claims 19 to 54 have been added. Claims 6 and 16 have been amended. Support for the amendments and newly added claims lies in the specification on page 2, lines 20 to 25, and lines 30 to 31; page 4, lines 20, 26 to 28; page 5, lines 1 to 3, 15 and 21 to 24. No new matter is believed added. A claim calculation sheet for the additional claims accompanies this response.

Attached herewith is a marked up version of the changes made to the claims by the current amendments. The attached page is captioned "Version to show changes made".

Applicants are also submitting, under separate cover, a supplemental Information Disclosure Statement, PTOL 1449 form and references cited therein for the Examiners review.

Double Patenting Rejection

Claims 6 to 9 and 16 to 18 are provisionally rejected under 35 USC §101 as claiming the same invention as that of Claim 1 to 42 of "copending Application No. 6,358,528". Applicants respectfully traverse this rejection.

It is presumed that this rejection is in error with respect to the reference of "a copending application No. 6358528" and is in fact a rejection over the claims of US Patent 6,358,528.

Applicant has amended Claim 16 to remove any overlapping subject matter with respect to the clavulanate contained therein, thereby rendering this rejection moot.

Reconsideration and withdrawal of the rejection under 35 USC §101 is respectfully requested.

Rejection under 35 USC §112

Claims 6 to 9, and 16 to 18 are rejected under 35 USC §112, second paragraph as being indefinite. Applicants respectfully traverses this rejection.

The specification, page 2, lines 20 to 31 clearly contemplates that in alternative embodiments the amount of amoxycillin in the core or casing layer may vary with the total amount being in either layer or spread between the two layers. While one embodiment is suggested to be about 25-75% of the total weight of the active and the other may be about 75-25% thereof, the invention should not be so limited to such a construction. In should be noted that in related patent, US 6,136,345 the term "a portion" of the amoxycillin is in the central core was utilized. The language in US Patent 6,136,345 is consistent with Applicants claimed invention herein in that all of the clavulanate therein is contained in the casing layer, as opposed to the core. It is only the Amoxicillin, which is spread between the two layers.

Applicants note, in contrast US Patent 6,358,528 is directed to having a portion of both the amoxycillin and clavulanate in the core and both components in the casing layer as well.

In view of these remarks, reconsideration and withdrawal of the rejection to the claims under 35 USC §112 is respectfully requested.

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit Account 19-2570 accordingly.

Respectfully submitted

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MARKED VERSION TO SHOW CHANGES MADE

Claims 19 to 54 have been added.

The following claims have been amended:

6 (amended) A tablet formulation according to Claim 16 wherein the core and the casing layer both comprise a compacted mixture of components [of compressed ingredients including the respective active materials].

16 (amended). A tablet formulation for oral administration comprising amoxycillin and clavulanate in a ratio of 30:1 to 1:1 in which a portion of the amoxycillin and [a portion of] all of the clavulanate is in a central core which is surrounded by a release-retarding coating layer and the remainder of the amoxicillin [and the remainder of the clavulanate] is in a casing layer surrounding the core, such that there is an initial quick release of amoxycillin and clavulanate from the casing layer and a sustained release of amoxycillin and clavulanate from the core.